

Appl. No. 10/814,123
Amdt. dated August 2, 2005
Reply to Office action of April 7, 2005

REMARKS/ARGUMENTS

Claim Amendments

By present amendment, the claims have been amended to enhance clarity and to correct clerical errors as described in greater detail hereinbelow. These amendments do not alter the scope of the claims in any way.

Claims 1, 39, 49 and 62 have been amended to replace "R¹, R² and R³" with "OR¹, OR² and OR³" as suggested by the Examiner. These claims have also been amended to replace the expression "may be" with the term "is".

Claim 30 has been amended to replace the expression "wherein he" with the expression "therein the".

Claims 41, 54, 56 and 57 have been amended to insert the definition of "OR¹, OR² and OR³" as found in amended claim 1.

Claim 51 has been amended to replace the word "reaction" with the word "reactivity".

Claims 55 and 59 have been amended to replace the expression "the anionic charge" with the expression "an anionic charge".

Claim 59 has been further amended to remove the expression "for example", along with the embodiments represented by this expression. The deleted embodiments have been reinserted as new claim 74.

The dependency of claim 63 has been changed from claim 61 to claim 62.

Claim 68 has been amended to clarify that compound 1 is GluconamideSi and compound 2 is MaltonamideSi.

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In summary, claims 1, 30, 41, 49, 51, 54-57, 59, 62, 63 and 68 have been amended and claim 74 is new. Claims 1-74 are pending in the present application.

The claim amendments have been made without prejudice and without acquiescing to any of the Examiner's objections. The Applicants submit that no new matter has been added to the claims as a result of these amendments and their entry is respectfully requested.

The Official Action dated April 7, 2005 has been carefully considered. It is believed that the claims submitted herewith and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

Claim Objections

35 U.S.C. §101

Claims 1-60 have been provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-60 of co-pending Application No. 10/647,174. Co-pending Application No. 10/647,174 is the parent application for the present application. The Applicants wish to inform the Examiner that co-pending Application No. 10/647,174 will be abandoned for failure to respond to the outstanding Office Action which will overcome this objection.

Claim Informalities

The Examiner has noted a number of informalities in claims 1-40, 49-53 and 62-67. In particular the Examiner has suggested that, in independent claims 1, 49 and 62, R¹, R² and R³ should be "OR¹, OR² and OR³". In response the Applicants have made this correction. The Examiner has further suggested that the word "he" in claim 30, line 1, should be "the" and that claim 63 should depend on claim 62 instead of claim 61. In response the Applicants have made these corrections.

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In light of the above corrections, the Applicants request that the Examiner's informality objections to the claims be withdrawn.

35 U.S.C. §112

The Examiner has objected to claims 1-61 and 68 under 35 U.S.C. §112, second paragraph, as being indefinite. The specific objections and the Applicants response thereto are as follows:

The Examiner has objected to the term "may be" in claims 1, 39 and 49. In response the Applicant has replaced the above noted term with the term "is" which overcomes this objection.

The Examiner has objected to claims 41, 54 and 56-58 for lacking a definition for "OR¹, OR² and OR³". In response, Claims 41, 54, 56 and 57 (and accordingly claim 58, dependent on claim 57) have been amended to insert the definition of "OR¹, OR² and OR³" as found in amended claim 1 which overcomes this objection.

The Examiner has objected to claim 51 for lacking an antecedent basis for the limitation "whose reaction". In response, the Applicant has replace the expression "whose reaction" with the expression "whose reactivity". The Applicants submit that reactivity is an inherent feature of a test substance, accordingly proper antecedent basis has been provided and the objection has been overcome.

The Examiner has objected to claims 55, 59 and 61 for lacking an antecedent basis for the limitation "the anionic charge". In response the Applicants have replaced the limitation "the anionic charge" with "an anionic charge" which overcomes this objection.

The Examiner has objected to the phrase "for example" in claim 59. In response, the Applicants have removed the expression "for example" from claim 59, along with

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the embodiments represented by this expression, which overcomes this objection. The deleted embodiments have been reinserted as new claim 74.

The Examiner has objected to the limitation "compound 1 and/or compound 2 in claim 68 as lacking sufficient antecedent basis. In response, claim 68 has been amended to clarify that compound 1 is GluconamideSi and compound 2 is MaltonamideSi which overcomes this objection.

In light of the above amendments, the Applicants request that the Examiner's objections to claims 1-61 and 68 under 35 U.S.C. §112, second paragraph, be withdrawn.

35 U.S.C. §102(g)

The Examiner has objected to claim 1-60 under 35 U.S.C. §102(g) as being anticipated by Zhang174 (US 10/647,174).

The Applicants submit that Zhang174, the parent patent application for the present application, was invented by the same inventors of the present application and, accordingly, Zhang174 is not a proper citation under 35 U.S.C. §102(g). Assignment data for both Zhang174 and the present application will be made available under separate cover.

In light of the above, the Applicants request that the Examiner's objections to claims 1-60 under 35 U.S.C. §102(g), be withdrawn.

35 U.S.C. §102(b)

Claims 40, 48 and 50 have been objected to under 35 U.S.C. §102(b) as being anticipated by Gill2001 (Chem. Mater. (2001), 13, pages 3404-3421). The Examiner's objection is respectfully traversed.

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Gill2001 does not describe siliceous materials prepared using organic polyol silane precursors in combination with one or more water soluble polymers or one or more compounds of Formula I. The Examiner contends that Gill2001 discloses a siliceous material prepared by hydrolysis/condensation of a poly(glyceryl silicate) (PGS) in the presence of water soluble polymers. The Applicants disagree with this interpretation of Gill2001. On page 3410, 1st column, of Gill2001, a review of the preparation of interpenetrating polymer network (IPN) composite sol gels is presented. Gill2001 teaches that these nano- or microcomposite polymers may be prepared by various methods including:

the combining of a sol-gel solution with a solution of a water-soluble polymer such as alginate, carrageenan, gelatin, agar, poly(vinyl alcohol), poly(ethylene glycol), poly(vinylpyrrolidone), or poly(glycidol), followed by sol-gel polymerization, and then organic polymer salt-cross-linking (alginate, carrageenan) or cryo-phase separation (PVA, gelatin, agar, and gelatin);

The Applicant submits that the sol-gel solutions referred to in the above passage were not prepared using organic polyol silane precursors or PGS. Further the Applicants submit that, prior to the priority date of the present application, the preparation of siliceous materials by hydrolyzing and condensing an organic polyol silane precursor in the presence of one or more water soluble polymers or one of more compounds of Formula I has not been described. The siliceous materials prepared using the inventive method of the present application have unique, advantageous properties including bimodal pore distribution, reduced shrinkage and protein stabilization (see page 12, lines 1-17, of the application as filed).

The courts have ruled:

It is elementary that an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device. *In re Donohue*, 226 USPQ 619, 621 (Fed. Cir. 1985) citing

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***Dalman v. Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983),
cert. denied 224 USQ 520 (1984).**

Since siliceous materials having the above-described advantageous properties were not described in Gill2001, the Applicants submit that claims 40, 48 and 50 are not anticipated by this reference.

In light of the above arguments, the Applicants request that the Examiner's objection to claims 40, 48 and 50 under 35 U.S.C. §102(b) be withdrawn.

35 U.S.C. §103(a)

The Examiner has objected to claims 1-5, 8-10, 38, 40-45 and 47-48 under 35 U.S.C. §103(a) as being obvious over Nakanishi688 (US 5,009,688) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598). The Applicants respectfully traverse this objection.

Nakanishi688 discloses a method of preparing siliceous materials by hydrolyzing and condensing a silicone alkoxide in the presence of a water-soluble organic polymer such as polyethylene oxide, etc. and undergoing phase separation. Nakanishi does not teach the use of organic polyol silane precursors in this method. Gill teaches the use of polyglyceryl silicate (PGS) in the preparation of siliceous materials. The Examiner contends that it would have been obvious to use a silicone glyceryloxide (presumably including the organic polyol silane precursors of the present invention) in the method of Nakanishi688 in view of the teachings of Gill. The Applicants respectfully disagree with the Examiner's conclusions.

The courts have ruled:

In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the

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proposed substitution, combination or other modification. *In re Lintner*, 173 USPQ 560, 562 (C.C.P.A. 1972).

The court has subsequently added that the reference teachings:

Appear to have suggested the *claimed subject matter*. *In re Rinehart*, 189 USPQ 143, 147 (C.C.P.A. 1976). [Emphasis added.]

Therefore, *ab initio*, the Examiner must show the present claims are suggested by the combination of Nakanishi688 and Gill.

The method of preparing siliceous materials taught in Nakanishi688 does not produce bimodal silica and Nakanishi688 is silent about the shrinkage properties of the materials produced therein. Nakanishi688 further makes no suggestion whatsoever to use organic polyol silanes as precursors for the preparation of the materials described therein. In fact, Nakanishi688 teaches away from the use of such precursors since in column 2, lines 31-34, it is taught that:

[a]s the metal alkoxide or its oligomer, the one having a relatively small number of carbon atoms such as a methoxy group, an ethoxy group or a propoxy group, is preferred. [emphasis added]

In light of the above passage a person skilled in the art would not be lead to believe that organic polyol silane precursors, such as diglycerylsilane used in the method of the present invention, which have a larger number of carbon atoms than metal alkoxides having a methoxy group, an ethoxy group or a propoxy group, would work in the method taught in Nakanishi688. Metal alkoxides having a methoxy group, an ethoxy group or a propoxy group are also not "polyols". Further, a person skilled in the art would have no way of knowing the unexpected properties of bimodal pore distribution, improved shrinkage properties and protein stabilization that are obtained when organic polyol silane precursors are used in combination with one or more water

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soluble polymers or one of more compounds of Formula I to prepare siliceous materials, since the siliceous materials prepared in Nakanishi688 do not have these properties.

The teachings in Gill go no further to provide motivation to a person skilled in the art to use organic polyol silane precursors in the method taught by Nakanishi688. First and foremost, the Applicants submit that Gill does not describe the use of organic polyol silane precursors in a method to prepare siliceous materials. Gill teaches (on page 8588, column 2) the use of poly(glyceryl silicate) (PGS) having a molecular formula of " $\text{SiO}_{1.2}\text{Glc}_{0.8}$ " which

was prepared as a stable, water soluble solid by the partial hydrolysis and condensation of tetramethyl orthosilicate (TMOS) to poly(methyl silicate) (PMS), followed by its transesterification with glycerol, in a one pot reaction catalyzed by hydrochloric acid or poly(antimony(III) ethylene glycoxide).

By using a partially hydrolyzed and polycondensed precursor, Gill loses control over the rate of silica hydrolysis and condensation. This is important in the method of the present invention, where, as taught on page 12, lines 1-4, a phase transition is to occur before gelation. Gill is, of course, silent about the occurrence of a phase transition, since Gill does not describe the use of water soluble polymers or compounds of Formula I in the preparation of siliceous materials. By using a non-hydrolyzed and non-condensed silane as a starting material, the method of present invention allows complete control over the entire hydrolysis and condensation procedure and therefore allows for the preparation of siliceous materials having the desirable properties of bimodal pore distribution, improved shrinkage properties and/or protein stabilization. It is clear from the teachings of Gill that siliceous materials having bimodal pore distribution are not produced since, Gill is silent about the use of the materials produced therein in chromatography, an application for which such a structure is desirable.

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The Federal Circuit has repeatedly warned that the requisite motivation to modify a prior art reference must come from the prior art, not Applicant's specification. It is, therefore, improper to:

[use] that which the inventor taught against its teacher. *In re Lee*, 277 F.3d at 1343 citing *W.L. Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir 1988).

The courts have also ruled:

There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure. *In re Dow Chem. Co.*, 5 USPQ2d 1529, 1531-32 (Fed. Cir. 1988).

It is clear that the Examiner has not met the burden to find motivation to modify Nakanishi688 and thereby render the present invention obvious. Therefore, not only was the solution taught by the present invention not known, but there is no suggestion to modify Nakanishi688, in particular in light of Gill, to solve the problem of the present invention.

Since all of the claims of the present application require the use of an organic polyol modified silane precursor and since, neither Nakanishi688 or Gill teach the use of such precursors, let alone the advantages of using such precursors (including bimodal pore distribution, improved shrinkage and protein stabilization), in methods of preparing siliceous materials, the invention as claimed in claims 1-5, 8-10, 38, 40-45 and 47-48 of the present application are not obvious in light of Nakanishi688 in view of Gill.

In light of the above arguments, the Applicants request that the Examiner's objection to claims 1-5, 8-10, 38, 40-45 and 47-48 under 35 U.S.C. §103(a) be withdrawn.

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The Examiner has objected to claims 1-5, 8-10, 40-45, 47-52, 54-55 and 56 under 35 U.S.C. §103(a) as being obvious over Nakanishi875 (US 5,624,875) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598). The Applicants respectfully traverse this objection.

Nakanishi875 discloses a method of preparing bimodal siliceous materials by hydrolyzing and condensing a silicone alkoxide in the presence of a water-soluble organic polymer such as polyethylene oxide, etc. and undergoing phase separation, followed by treatment of the resulting material with "pore forming" compositions. Nakanishi does not teach the use of organic polyol silane precursors in this method. Gill teaches the use of polyglyceryl silicate (PGS) in the preparation of siliceous materials. The Examiner contends that it would have been obvious to use an silicone glyceryloxyde (presumably including the organic polyol silane precursors of the present invention) in the method of Nakanishi675 in view of the teachings of Gill. The Applicants respectfully disagree with the Examiner's conclusions.

The courts have ruled:

In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed substitution, combination or other modification. *In re Lintner*, 173 USPQ 560, 562 (C.C.P.A. 1972).

The court has subsequently added that the reference teachings:

Appear to have suggested the *claimed subject matter*. *In re Rinehart*, 189 USPQ 143, 147 (C.C.P.A. 1976). [Emphasis added.]

Therefore, *ab initio*, the Examiner must show the present claims are suggested by the combination of Nakanishi875 and Gill.

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Nakanishi875 is silent about the shrinkage properties of the materials produced therein. Nakanishi875 further makes no suggestion whatsoever to use organic polyol silanes as precursors for the preparation of the materials described therein. In fact, Nakanishi875 teaches away from the use of such precursors since in column 5, lines 61-63, it is taught that:

Silicon alkoxides which are desirable in the preparation of the gel are tetramethoxysilane, tetraethoxysilane and polymerized derivatives of these compounds.

Tetramethoxysilane and tetraethoxysilane contain far fewer carbon atoms than the organic polyol silane precursors of the present invention and are not "polyols". Further, a person skilled in the art would have no way of knowing the unexpected properties of improved shrinkage properties and protein stabilization that are obtained when organic polyol silane precursors are used in combination with one or more water soluble polymers or one of more compounds of Formula I to prepare siliceous materials, since the siliceous materials prepared in Nakanishi875 do not have these properties therefore a person skilled in the art would not be lead by the teachings in Nakanishi875 to use organic polyol silane precursors in the method taught therein.

Regarding the pore distribution of the siliceous materials produced in Nananishi875, it is taught that, in order to get a bimodal pore distribution (i.e. the presence of both mesopores and macropores), the materials produced by the hydrolysis of condensation of metalorganic compound in the presence of a water soluble polymer must be treated with a liquid which can dissolve said organic component (see column 3, lines 37-38). Nakanishi875 teaches in column 2, lines 34-36, that such liquids include, for example:

an aqueous solution having appropriate acid or base concentrations, or an aqueous solution containing fluoride ions.

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Such solutions would not be compatible with the entrapment of sensitive biomolecules, such as proteins, within the matrixes prepared by the method of Nakanishi875. In contrast, the method of the present invention produces siliceous materials having a bimodal pore distribution without the use of harsh chemical conditions rendering the method of the present invention, advantageously, biomolecule compatible. These advantages would in no way be apparent to a person skilled in the art from reading Nakanishi875.

Further, and as mentioned above, the teachings in Gill go no further to provide motivation to a person skilled in the art to use organic polyol silane precursors in the method taught by Nakanishi875. First and foremost, the Applicants submit that Gill does not even describe the use of organic polyol silane precursors in a method to prepare siliceous materials. Gill teaches (on page 8588, column 2) the use of poly(glyceryl silicate) (PGS) having a molecular formula of " $\text{SiO}_{1.2}\text{Glc}_{0.8}$ " which

was prepared as a stable, water soluble solid by the partial hydrolysis and condensation of tetramethyl orthosilicate (TMOS) to poly(methyl silicate) (PMS), followed by its transesterification with glycerol, in a one pot reaction catalyzed by hydrochloric acid or poly(antimony(III) ethylene glycoxide).

By using a partially hydrolyzed and polycondensed precursor, Gill loses control over the rate of silica hydrolysis and condensation. This is important in the method of the present invention, where, as taught on page 12, lines 1-4, a phase transition is to occur before gelation. Gill is, of course, silent about the occurrence of a phase transition, since Gill does not describe the use of water soluble polymers or compounds of Formula I in the preparation of siliceous materials. By using a non-hydrolyzed and non-condensed silane as a starting material, the method of present invention allows complete control over the entire hydrolysis and condensation procedure and therefore allows for the preparation of siliceous materials having the desirable properties of

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bimodal pore distribution, improved shrinkage properties and/or protein stabilization. It is clear from the teachings of Gill that siliceous materials having bimodal pore distribution are not produced since, Gill is silent about the use of the materials produced therein in chromatography, an application for which such a structure is desirable.

The Federal Circuit has repeatedly warned that the requisite motivation to modify a prior art reference must come from the prior art, not Applicant's specification. It is, therefore, improper to:

[use] that which the inventor taught against its teacher. *In re Lee*, 277 F.3d at 1343 citing *W.L. Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir 1988).

The courts have ruled:

There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure. *In re Dow Chem. Co.*, 5 USPQ2d 1529, 1531-32 (Fed. Cir. 1988).

It is clear that the Examiner has not met their burden to find motivation to modify Nakanishi875 and thereby render the present invention obvious. Therefore, not only was the solution taught by the present invention not known, but there is no suggestion to modify Nakanishi875, in particular in light of Gill, to solve the problem of the present invention.

Since all of the claims of the present application require the use of an organic polyol modified silane precursor and since, their Nakanishi875 or Gill teach the use of such precursors, let alone the advantages of using such precursors (including bimodal pore distribution, improved shrinkage and protein stabilization), in methods of preparing siliceous materials, the invention as claimed in claims 1-5, 8-10, 40-45, 47-52, 54-55 and 56 of the present application are not obvious in light of Nakanishi875 in view of Gill.

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In light of the above arguments, the Applicants request that the Examiner's objection to claims 1-5, 8-10, 40-45, 47-52, 54-55 and 56 under 35 U.S.C. §103(a) be withdrawn.

Claim 38 has been objected to under 35 U.S.C. §103(a) as being obvious over Nakanishi875 (US 5,624,875) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598) and as evidenced by Barkin (US 3,374,103).

Claim 38 depends on claim 1 and specifies that the conditions suitable for the hydrolysis and condensation of the precursor to a siliceous material include a pH in the range of about 4-11.5 in aqueous solutions and with optional sonication to assist in dissolution. The Examiner has combined the teaching in Barkin that the pKa of acetic acid is 4.76 with the teaching in Nakanishi875 that hydrolysis/condensation of a silicone alkoxide is carried out in a 0.001 mol/l aqueous solution of acetic acid to conclude that the pH of the reaction medium in Nakanish875 should fall with in the range claimed in claim 38 of the present application.

The Applicants submit that the arguments provided above that teachings in Nakanish875 in view of Gill do not render the claims in the present application obvious (in particular claim 1 upon which claim 38 depends), apply to the Examiner's objection to claim 38 described above.

Accordingly, the Applicants submit that claim 38 is not obvious over Nakanishi875 (US 5,624,875) in view of Gill (J. Am. Chem. Soc., (1998), 120, 8587-8598) and as evidenced by Barkin (US 3,374,103) and request that the Examiner's objection to this claim under 35 U.S.C. §103(a) be withdrawn.

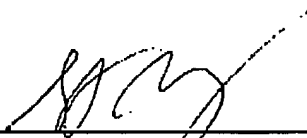
In view of the foregoing arguments and amendments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater

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detail, the Examiner is kindly requested to contact the undersigned by telephone at (416) 957-1683 at the Examiner's convenience.

Respectfully submitted,

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